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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/765,580

01/27/2004

Marina V. Backer

102108-300

1535

27267 7590 02/05/2007

WIGGIN AND DANA LLP
ATTENTION: PATENT DOCKETING
ONE CENTURY TOWER, P.O. BOX 1832
NEW HAVEN, CT 06508-1832

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1649

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/765,580

Applicant(s)

BACKER ET AL.

Examiner

Robert C. Hayes, Ph.D.

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 6-10, 15-21, 23 and 25 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22 and 24 is/are allowed.
- 6) ☒ Claim(s) 1-5 and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/27/04.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-5, 11-14, 22 & 24) in the reply filed on 11/13/06 is acknowledged.

Claims 6-10, 15-21, 23 & 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/06.

Allowable Subject Matter

2. Claims 22 & 24 are allowed.

Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 & 11-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes the human VEGF nucleic acid of SEQ ID NO: 10 and the Shiga-like toxin 1 (SLT-1) nucleic acid of SEQ ID NO: 9. No other nucleic acid molecules are described, especially as it relates to "mutated versions thereof", except for a "double mutant A-

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subunit with Y114S and R170L amino acid substitutions that... [do] not affect its folding as judged by antigenic properties” being mentioned on page 9 of the specification. However, how this double mutation relates to the nucleic acid molecule of SEQ ID NO: 9 is unknown, and not described. Page 18 of the specification further states that “[a]s used herein, VEGF refers to polypeptides having amino acid sequences of native VEGF proteins, as well as modified sequence, having amino acid substitutions, deletions, insertions or additions of the native protein..., but are not limited to, VEGF121, VEGF165, VEGF189, VEGF209”, which are further not described. Page 19 of the specification then states that “[i]t is understood that differences in amino acid sequences can occur among VEGFs of different species as well as among VEGFs from individual organisms or different species. Reference to VEGFs is also intended to encompass proteins isolated from natural sources as well as those made synthetically, as by recombinant means or possibly by chemical synthesis”.

The issue then becomes that although the specification only describes the single specific *human* species polynucleotide of SEQ ID NO: 10 (and the Shiga-like toxin molecule of SEQ ID NO: 9), “truncated” versions of either of these SEQ ID NOs can reasonably be visualized. However as indicated above, no generic functional “mutated” sequences can reasonably be visualized by the skilled artisan (i.e., as it relates to VEGF & SLT-1 “*mutated versions thereof*”). Likewise, no sequences from any VEGFs from “different species” can reasonably be visualized, because none are described. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making

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the claimed product, or any combination thereof. Thus, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus of nucleic acids encoding fusion proteins because one skilled in the art can not structurally visualize or predict what critical encoded amino acid residues would structurally characterize the genus of nucleic acids encoding a functional VEGF-SLT-1 fusion protein, as currently claimed; thereby, not reasonably meeting the written description requirements of 35 U.S.C. 112, first paragraph. See MPEP 2163.

4. Claims 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is ambiguous what exactly is being claimed because base claim 11 (1) recites "or a truncated or mutated versions thereof", whereas "the nucleic acid sequence of SEQ ID NO: 11" is a specific sequence, and does not encompass any "truncated or mutated versions thereof", by definition; thereby, being contradictory.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'R. Hayes' with a checkmark-like flourish at the end.

Robert C. Hayes, Ph.D.
January 22, 2007

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER